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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,871	03/26/2001	Felix Frey	27656/37082	1259

7590 07/02/2002
Jeffrey S Sharp
6300 Sears Tower
233 South Wacker Drive
Chicago, IL 60606-6402

EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 07/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,871

Applicant(s)

FREY ET AL.

Examiner

Quang Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-19 and 30-31, drawn to a compound comprising a steroid hormone stably linked to a DNA interacting molecule, and a method for the preparation of the same compound.

Group II, claims 20-24 and 27-28, drawn to a complex comprising a steroid hormone stably linked to a DNA interacting molecule complexed to a nucleic acid molecule, a method for the preparation of the complex and use of the complex for introducing a nucleic acid molecule into the nucleus of a cell.

Group III, claims 25-26, drawn to a cell transfected with a complex comprising a steroid hormone stably linked to a DNA interacting molecule complexed to a nucleic acid molecule and use of the same cell for the medical treatment of a human.

Group IV, claim 29, drawn to an assay comparing the expression of expressible genes between cells transfected with the DNA-complex of the present invention and non-transfected cells.

The technical feature linking Groups I to IV appear to be that they all relate to a conjugate of a steroid hormone with a chemical group that binds to nucleic acid molecule, particularly DNA.

However, WO 96/18372 (IDS) already discloses the conjugation of androsterone or other steroids to a cationic group that interacts with DNA or RNA molecule (see Summary of invention, particularly pages 26-30). Additionally, WO 96/03875 (IDS)

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teaches a composition comprising a steroid moiety (e.g., androgens, estrogens, synthetic androgens and estrogens) being covalently linked to a polycationic material (e.g., polylysines, polyarginines, protamines) that can complex to a nucleic acid molecule (see Summary of invention, particularly page 11 and example 1).

Therefore, the technical feature linking the inventions of Groups I to IV does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not differentiate the claimed subject matter as a whole over the prior art. Since according to Rule 13.2 PCT the presence of such a common or corresponding special technical feature is an absolute prerequisite for unity to be established, and given that there does not appear to be any other technical feature common to the claimed subject matter as a whole which might be able to fulfill this role, the currently claimed subject matter lacks unity according to Rule 13.1 PCT.

Consequently the claimed subject matter was broken up into the aforementioned Groups of Invention. The inventions are distinct, each from the other for the following reasons:

The compound of Group I differs from the complex of Group II because it does not contain a nucleic acid molecule which is present as a component of the complex of Group II. Accordingly, the methods for preparing these different compositions in Groups I and II require different starting materials and different method steps. Both the compound of Group I and the complex of Group II differ from the transfected cell of Group III because the transfected cell is a living entity having a different chemical composition from those of Groups I and II. The method of Group IV is distinct from the

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methods of Groups II and III because it differs in the method steps and desired end-results that require different technical considerations. It is noted that the method of Group IV does not require any therapeutic effects contemplated by Applicants.

Because these inventions are distinct for the reasons set forth above, it would be unduly burdensome for the examiner to search and/or consider the patentability of all of the inventions in a single patent application. Therefore, restriction for examination purposes as indicated is proper.

Should Applicants elect the invention of Group I, it contains claims directed to the following patentably distinct species:

Claims 1-19 and 30-31 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named steroid hormone as listed in the Markush group of claim 12.

→ Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Claims 1-19 and 30-31 are generic to a plurality of disclosed patentably distinct species comprising:

A specifically named DNA interacting molecule as listed in the Markush group of claim 13.

Applicant is required under 35 U.S.C. 121 to elect a specifically named species as indicated above.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Dave Nguyen, may be reached at (703) 305-2024, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tracey Johnson, whose telephone number is (703) 305-2982.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636.

Quang Nguyen, Ph.D.


REMY YUCEL, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600